



Certificate of EU product notification

Herewith we confirm that

MT Promedt Consulting GmbH Altenhofstraße 80 66386 St. Ingbert Germany

has taken over the function of an European Authorized Representative according to the requirements of Article 10 of the IVDD 98/79/EC for

BioNote, Inc. 22, Samsung 1-ro 4-gil, Hwaseong-si, Gyeonggi-do 18449 Republic of Korea

MT Promedt Consulting GmbH has made the product notification at the relevant competent authority according to Article 10(3).

The in vitro diagnostic medical devices of the manufacturer, covered by the notification, are listed in Annex I of this certificate.

This certificate does not attest the conformity of the medical devices with the above mentioned directive. The conformity is stated in the respective product-related Declarations of Conformity signed under the sole responsibility of the manufacturer.

8 June 2020

Dr. Michael Rinck

- Managing Director -

Enclosure Annex I





BioNote, Inc.

Annex I

to "Certificate of EU Product Notification"

(List of CE marked Products)

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Internal Reference Number	Product Name (Model name)	Registration Number (at the German CA/DIMDI) DE/CA70/40838/	Product Category (EDMS)	EDMS Code Description	Classification Annex
BIN-01	NowCheck COVID- 19 Ag Test	156134	15 70 90 90 00	Other Other Virology Rapid Tests	Other IVD / Annex III
BIN-01-01	NowCheck COVID- 19 IgM/IgG Test	156134	15 70 90 90 00	Other Other Virology Rapid Tests	Other IVD / Annex III
BIN-02	NowCheck COVID- 19 Ag Control	156138	15 50 01 04 00	Other Virology Controls - Inf.Imm.	Other IVD / Annex III
BIN-02-01	NowCheck COVID- 19 IgM/IgG Control	156138	15 50 01 04 00	Other Virology Controls - Inf.Imm.	Other IVD / Annex III

8 June 2020

Dr. Michael Rinck

- Managing Director -